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09/516,493	03/01/2000	Maureen J. Charron	96700/613	3363

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EXAMINER	
KAUSHAL, SUMESH	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/516,493	Applicant(s) CHARRON ET AL.	
	Examiner Sumesh Kaushal Ph.D.	Art Unit 1636	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.*

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)*
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 012/12/02 has been entered.

Claims 44-72 are canceled.
Claims 73-115 are newly filed.
Claims 73-115 are pending and are examined in this office action.

▷ *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm). Each amendment document that includes a change to an existing claim, or submission of a new claim,* ***must include a complete listing of all claims*** *in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.*

Claim Rejections - 35 USC § 101 & 35 USC § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 73-115 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted **utility** or a well established utility, for the same reasons of record as set forth in the office action mailed on 08/28/02.

2. Claims 73-115 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know **how to use the claimed invention,** for the same reasons of record as set forth in the office action mailed on 08/28/02.

Note: Lack of Utility and Enablement rejections are discussed together below.

Nature Of Invention: The invention relates to isolated nucleic acid sequences that has glucose transport activity (GLUT).

Breadth Of Claims And Guidance Provided By The Inventor:

The instant claims are drawn to isolated nucleic acid sequences of SEQ ID NO:6, 9 and 11 which encodes the amino acid of SEQ ID NO: 7, 10 and 12. The scope of invention as claimed encompasses isolated nucleic acid sequences that hybridizes under high stringency conditions to the nucleic acid sequences encoding the amino acid sequence of SEQ ID NO: 7, 10 and 12 and encodes a polypeptide having at least 85-98% homology with amino acid sequence of SEQ ID NO: 7, 10 and 12. In addition the claims are drawn to isolated nucleic acid sequence that encodes a polypeptide comprising 12 transmembrane domains and has a molecular weight of approximately 32.6kD.

The specification hypothesize that GLUTx is a novel insulin responsive and glycemia sensitive glucose transporter/sensor/receptor that is instrumental in the maintenance of whole body glucose homeostasis in GLUT4 null mice (spec. page 3, line 13; page 33, line 15). The

specification further states that GLUTx could be similar to SNF3 and RGT2 of *Saccharomyces,* which are similar in structure to glucose transporters and can transport glucose but not in sufficient quantities. The specification further teaches that GLUTx polypeptide have 45% and 40% sequence similarity with GLUT4 and SNF3/RGT2 of *Saccharomyces* respectively (spec. page 33, example-6). The specification further disclosed that the preliminary in-situ hybridization studies indicates that GLUTx is expressed in the cerebellum and hippocampus of GLUT4 null mice and these studies suggest that GLUTx may function as glucose sensor or receptor in the brain (spec. page 38, example-9).

State Of Art And Predictability:

It is known in the art that glucose transporter/sensor/receptor (GLUT) have very divergent functions. Glucose transport across biological membranes requires the presence of specific integral membrane proteins in mammals that fall into two classes i) Na+/glucose cotransporters and ii) SGLT1 and SGLT2. These transporters are involved in glucose absorption into the body, glucose uptake by the brain, storage in liver, insulin-dependent uptake in muscles and adipocytes, and glucose sensing by pancreatic cells. Furthermore, the GLUTs form a family of highly related hexose transport proteins that belongs to a larger sugar transport superfamily consisting of more than 133 members distributed in a wide variety of species. In addition studies performed with knockout mice have revealed the existence of glucose transport activity that could not be accounted for by any known GLUTs (Ibberson et al, JBC, 275(7):4607-4612, 2000, page 4607, ref of record). Furthermore, it is known that glucose transporter (GLUT)1 isoforms differ in their expression in different tissues, in their kinetic characteristics and in their substrate specificity. For example, GLUT1 mediates glucose transport into erythrocytes and through the blood-brain barrier, and appears to provide a basal supply of glucose for most cells. GLUT2 catalyzes glucose uptake into the liver, and is an essential component of the glucose sensing mechanism of the pancreatic cell. GLUT3 is predominantly expressed in neuronal cells, whereas GLUT4 is exclusively found in muscle and adipose tissue. GLUT5 mediates transport of fructose, but probably not glucose, in intestine and spermatozoa. The diverse tissue distribution and the specific functions of GLUT1-GLUT5 appear to indicate that these genes control glucose uptake in mammalian tissues (Doege et al, J. Biol. Chem. 275(21):16275-16280, 2000).

In addition, the amino acid sequences encoding **GLUTX1**-consensus sequence comprises 478 amino acids, whereas the disclosed SEQ ID NO:7 (human) is only 453, SEQ ID NO:10 (mouse) is only 165 and SEQ ID NO:12 (rat) is only 94 amino acid long (see Gene Bank AN: AAB66939 in WO200104145, 2001. *see PTO sequence search report, ref of record*). It is unclear how the partial sequences (as disclosed) would encode any GLUTx-like activity. At best the instant specification only disclose pieces of GLUTx-like amino acid sequences isolated from hum mouse and rat. However, the specification fails to disclose that these partial sequences have any GLUTx-like activity explicitly or implicitly as putatively considered by the instant specification. Furthermore, the Office sequence search using the disclosed amino acid sequences matches with **GLUTX3** consensus sequences (AN: AAB66941) SEQ ID NO:7 (40%), SEQ ID NO:10 (31%) and SEQ ID NO:12 (42%), but only with very low sequence similarity. Similarly, SEQ ID NO:7 (23%) and SEQ ID NO:12 (30%) matches with GLUTX2 amino acid sequences (AN:AAB66940, AAB66936 respectively), but only with very low sequence similarity. Further inspection of the comparison shows limited if any areas of conservation between the two sequences. In instant case the recited SEQ ID NO(s) are simply computer-generated hypotheses, wherein no biological function has been established. Therefore one skilled in the art would not readily attribute any particular glucose transporter/sensor/receptor-like activity encoded by the instant nucleic acid in view of the low sequence similarity and the lack of sequence conservation therein.

In addition, it is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The recited SEQ ID NO(s) are simply computer-generated hypothesis because no biological functions have been established. The mere identification of critical regions (like 12 transmembrane domains) or molecular weight (32.6kD) would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues. see Ngo, in The Protein Folding Problem and Tertiary Structure Prediction, Merz et al. (eds.), Birkhauser Boston: Boston, MA,

pp. 433 and 492-495, 1994). Rudinger (in Peptide Hormones, Parsons (ed.), University Park Press: Baltimore, MD, pp. 1-7, 1976).

Quantity Of Experimentation Required:

The instant invention is not considered to have a specific and/or substantial utility because the specification fails to establish that the disclosed polynucleotide sequences as claimed encodes a protein which is a member of glucose transporter/sensor/receptor family as shown by structural and/or functional properties. In view of such and the fact that glucose transporter/sensor/receptors differ substantially in activity, it is unclear that any glucose transporter/sensor/receptor could be attributed to the deduced amino acid sequence of the claimed nucleic acid. Since the instant specification fails to disclose an assay to measure the biological activity of GLUTx polypeptides (as claimed), the only unlimited use for the disclosed polnucloetide sequences would be the determination of what is the biological activity of the claimed polynucleotides and further scientific evaluation on how to use the discovered protein activity.

Even though specification alleges that the instant nucleic acid encodes for protein belonging to glucose transporter/sensor/receptor family, no sequence comparisons are taught by specification as filed, nor are any specific similarities to other glucose transporter/sensor/receptor expressing proteins (GLUT 1-5) are disclosed, such as common areas of conservation. The specification fails to teach that the polypeptide encoded by claimed SEQ ID NO: 7, 10 and 12 even have the biological activity of any glucose transporter/sensor/receptor-like protein explicitly or implicitly as putatively considered by the specification. In addition, the specification fails to disclose the role of the claimed glucose transporter/sensor/receptor (GLUTx) polypeptide in any disease. It is unclear from the instant disclosure whether the disease would be the result of the loss of GLUTx bearing polypeptide activity or is the result of altered protein function. It is even unclear whether the treatment of the disease associated with polypeptide as claimed would require increase or decrease in the expression of claimed GLUTx protein. Considering the state of art *(supra),* the only immediate apparent utility for the instant invention would be its further scientific characterization as a putative glucose transporter/sensor/receptor. Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The quantity of experimentation required would include the functional

characterization of polypeptide encoded by SEQ ID NO: 7, 10 and 12 as a protein having glucose transporter/sensor/receptor-like activity and use thereof. Therefore, the asserted use for the claimed nucleic acid is not considered to support by either a specific and/or substantial utility, since no function can be ascribed to the gene.

Response to arguments (Utility and Enablement)

The applicant argues that the claimed invention has utility as marker of hyperglycemia and diabetes and diagnostic of breast cancer. The applicant further argues that an applicant need to provide only one credible assertion of specific and substantial utility for each claimed invention (response, page 8, para.2).

However, this is found NOT persuasive applicant's argument alone cannot take place of evidence lacking in the record (see In re Scarbrough 182 USPQ, (CCPA) 1979). The 2-3 folds up-regulation of the claimed nucleic acid sequences in the liver of diabetic and hypoglycemic animal is not specific, since the instant specification clearly discloses the expression of GLUTx mRNA in variety of tissues including brain, liver and testis of both normal and diabetic rats (spec. page 39). In addition use of GLUTx antibodies to identify the breast cancer is not specific since GLUTx protein was also found in testis, heart fat, liver, diaphragm and soleus muscles in both GLUT4 null and wild type mice. Furthermore, it is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (*See Brenner v. Manson , 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

In instant case determining biological activity of polypeptide base upon a low sequence similarity is not routine in the art and without sufficient guidance to a specific therapeutic gene the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the

broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The quantity of experimentation required would include the functional characterization of polypeptide encoded by SEQ ID NO: 7, 10 and 12 as a protein having glucose transporter/sensor/receptor (GLUT) like activity and use thereof.

3. Claims 80-91, 95-97, 101-103, 107-109 and 113-115 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, **had possession of the claimed invention** for the same reasons of record as set forth in the office action mailed on 08/28/02.

The invention of the instant claims encompasses any and all natural and non-natural variants of nucleic acid sequences (with 85-98% sequence variation) encoding the amino acid sequence of SEQ ID NO:7, 10 and 12 (GLUTx) obtained from any and all organisms. At best, the specification discloses only one variant each for human, mouse and rat within the scope of genus comprising the nucleic acid sequences of SEQ ID NO:6, 9 and 11. The specification proposes to discover other members of the genus using high stringency hybridization conditions. However, there is no description of mutational sites that exist in nature, and there is no description how the structure of identified nucleic acid sequences variants would relates to the structure of any strictly neutral alleles. In addition, the glucose transporter/sensor/receptor (GLUTs) included members that would expected to have widely divergent functional properties (*Supra)*. The general knowledge in the art glucose transporter/sensor/receptor does not provide any indication as how the structure of one allele is representative of other unknown amino acid sequences having concordant or discordant functions. The commons attributes of all glucose transporter/sensor/receptor are not described, and identifying attributes of individual GLUTx-like protein other than SEQ ID NO:6, 9 and 11 are not described. The nature of glucose transporter/sensor/receptor is that they are variant structures and functions of others (*supra*). At best the specification only disclosed nucleic and amino acid sequences encoding human, mouse

and rat GLUTx polypeptide (SEQ ID NO:7, 10, 12). Furthermore, the amino acid sequences encoding GLUTX1-consensus sequence comprises 478 amino acids, whereas the disclosed SEQ ID NO:7 (human) is only 453, SEQ ID NO:10 (mouse) is only 165 and SEQ ID NO:12 (rat) is only 94 amino acid long (see Gene Bank AN: AAB66939 in WO200104145, 2001. *see PTO sequence search report*). At best the instant specification only disclose pieces of GLUTx-like amino acid sequences isolated from human, mouse and rat. It is unclear how the partial sequences (as disclosed) would encode any GLUTx-like activity explicitly or implicitly as putatively considered by the instant specification.

In addition, the instant specification fails to disclose any and all variant of GLUTx polypeptides, which has any glucose transporter/sensor/receptor-like activity from any and all organisms. The invention as claimed encompass nucleic acid sequences, which are alt least 85-98% to the claimed GLUTx sequences. The variation as claimed even encompasses the conserved motifs that are germane to any glucose transporter/sensor/receptor-like activity. It is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted, and the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. The variants as claimed are simply computer generated hypothesis because no biological functions has been established even for SEQ ID NO:7, 10 and 12. The mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues *(supra)*. Therefore, the applicant has not presented enablement commensurate in scope with the claims.

Response to arguments (Written Description)

The applicant argues that nucleic acid sequences are described in SEQ ID NO: 6, 9 and 11; and amino acid are described in SEQ ID NO: 7, 10 and 12. The applicant further argues that the specification disclosed high stringency conditions to screen variants, therefore one skill in the art would conclude that the inventors had possession of the claimed invention (response, page 9 para.2).

However, this is found NOT persuasive because at best the specification only disclosed pieces of GLUT-like amino acid sequences isolated from human, mouse and rat comprising the claimed SEQ ID NO:6, 9 and 11 respectively. It is unclear how the partial sequences (as disclosed) would encode any GLUT-like activity explicitly or implicitly as putatively considered by the instant specification. The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see In re Shokal 113USPQ283(CCPA1957); Purdue Pharma L. P. vs Faulding Inc. 56 USPQ2nd 1481 (CAFC 2000). In addition possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *See, e.g., Pfaff v. WellsElectronics, Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).* In claims to genetic material, generic statement such as "vertebrate insulin cDNA" or mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material (*Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406).* In the instant case the variants of nucleic acid encoding the amino acid sequences has been defined only by a statement of function of an unknown glucose transporter/sensor/receptor (GLUTx) like protein which conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics (see specification page 3, lines 13-22). According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 73-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 recites the limitation "the nucleic acid" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 74 recites the limitation "the nucleic acid" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 75 recites the limitation "the nucleic acid" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 81-87, 82-91 and 114-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (EST ID:H34451, ID:H34372, 1998, *see PTO Sequence search report.* and PNAS 92:8303-8307, 1995, both ref. of record). The cited art teaches a nucleic acid sequence which matches 99.1% to the nucleic acid sequence of SEQ ID NO:11 (encoding SEQ ID NO:12) and 95.5% with the nucleic acid sequence of SEQ ID NO:9 (encoding SEQ ID NO:10) of instant application. In addition, the cited prior art teaches cloning of nucleic acid sequences in a plasmid vector. Thus the cited art clearly anticipated the invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
PATENT EXAMINER

SUMESH KAUSHAL
PATENT EXAMINER